



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Van Dyke, et al.

Serial No.: 09/899,372

Filed: July 2, 2001

For: SOLUBLE KERATIN PEPTIDE

Group Art Unit: 1615

Examiner: Isis A D Ghali

Atty. Dkt. No.: KER020/4-005CON

Confirmation No. 3035

CERTIFICATE OF MAILING

I, certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

October 11, 2006

Date

Timothy S. Corder

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby

authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account Vinson & Elkins  
L.L.P. Deposit Account No. 22-0365/KER020/4-005CON.

## REMARKS

This supplement of the Information Disclosure Document filed on April 28, 2006, provides an explanation of the foreign language references that were not considered by the Examiner. The Examiner is requested to consider these references and to indicate that they have been considered on the attached form PTO-1449. Copies of these references are also found in the opposition proceedings filed in the Information Disclosure Document filed on April 28, 2006, as reference C130.

### **RU 2007 181 Cl (DI)**

Please note that a copy of the cover page of RU-C1-2 007 181 is enclosed.

The claims of RU-C1-2 007 181 read as follows:

1. A method for the manufacture of a biological material as a basis for soft and hard medicaments and cosmetics comprising the alternative treatment with alkaline and acidic solutions, neutralization, packaging and sterilization the product, to provide new agents and to avoid allergic reactions as a starting material keratin containing materials is used, which is treated with a solution having a pH of 10.8 to 13.8 and a liquid phase coefficient of 10-35 and containing 0.1 to 5.0 % sodium peroxide, 1 to 10 % sodium chloride and 0.5 to 5.0 % hydrogen peroxide at 16 to 32 °C for 4 to 24 hours, after washing and flooding with a solution having a pH of 1.2 to 2.9, a liquid phase coefficient of 5-10 and containing 0.1 to 5.0 % ortho-phosphoric acid and 0.1 to 3.0 % nitric acid at 16 to 32 °C for 4 to 24 hours said material is treated again with said alkaline solution having a liquid phase coefficient of 10-25, and after neutralization adjusting the pH to 6.0 to 7.0, homogenizing, filtering and adding ethanol to a concentration of 10 to 40 % to the filtrate and precipitating the desired product.
2. The method of claim 1, wherein the precipitate is dried and grinded to a particle size of up to 3 mm to provide a universal product for long term storage and transportation and also for the manufacture of other products.
3. The method of claim 1, wherein a 0.1 - 3.5% solution is made and lyophilizing said solution for providing a sponge-like product.
4. The method of claim 1, wherein a 0.1 - 2.5% solution is made and dried by heating up to 95°C for providing a film-like product.

The description of RU 2007 181 Cl provides some additional information as follows:

RU 2007 181 Cl seems to disclose a powdered keratin material having a particle size of up to 3 mm for treating skin and connective tissue or for use as a semi-finished product in the pharmaceutical and cosmetic industry (tablets, creams etc.) (page 3, right column, lines 49-59).

The material of DI is obtained by a method comprising the following steps (page 3, right column, lines 1-34, page 4, left column, lines 3-56):

- a) treating a keratin-containing starting material with a solution having a pH of 10.8 to 13.8 and a liquid phase coefficient of 10-35 and containing 0.1 to 5.0 % sodium peroxide, 1 to 10 % sodium chloride and 0.5 to 5.0 % hydrogen peroxide at 16 to 32 °C for 4 to 24 hours;
- b) washing said material two times with water (using a volume of 10 to 20 times the volume of the keratin-containing starting material);
- c) flooding said material with a solution having a pH of 1.2 to 2.9 and a liquid phase coefficient of 5-10 and containing 0.1 to 5.0 % ortho-phosphoric acid and 0.1 to 3.0 % nitric acid at 16 to 32 °C for 4 to 24 hours;
- d) treating said material with a solution having a pH of 10.8 to 13.6 and a liquid phase coefficient of 10-25 and containing 0.1 to 4.0 % sodium peroxide, 1 to 8 % sodium chloride and 0.3 to 4.0 % hydrogen peroxide at 16 to 32 °C for 4 to 24 hours;
- e) neutralizing the obtained composition with a solution having an pH of 6.0 to 7.0 containing an inorganic acid;
- f) washing said material three times with dist. water;
- g) adding 25 to 100 volumes of 0.05 to 0.50 % sodium hydroxide for 4 to 24 hours;
- h) adjusting the pH to 7.0 to 9.0;
- i) homogenizing and filtering;
- j) adding ethanol to a concentration of 10 to 40 % to the filtrate, and
- k) precipitating the desired product.

The keratin powders of all examples are bright cream in color (middle of Tab. 2).

Page 4, left column, lines 31-34 discloses that the keratin decomposes to molecular and higher molecular compositions (macro particle fibrils 30-250 micrometer).

#### **DE-A1-32 33 665 (D4)**

The equivalent to DE-A1-32 33 665 is US 4,530,829, a copy of which was submitted as reference A8 with the Information Disclosure Statement submitted on July 2, 2001. Please note that the wording of the abstract and the description of both documents is identical.

The claims of DE-A1-32 33 665 read as follows:

1. A hair treatment composition comprising the following two ingredients a) and b):
  - a) polyphenol compound: 0.001-5.0 wt.% and
  - b) chelating agent: 0.01-5.0 wt.%.
2. A hair treatment composition comprising the following three ingredients a), b) and c):
  - a) polyphenol compound: 0.001-5.0 wt.%,
  - b) chelating agent: 0.01-5.0 wt.% and
  - c) at least one decomposition derivative of keratin material selected from the group consisting of (1) hydrolysates of keratin material, (2) alkali salts of decomposition products obtained by oxidation of keratin material, and (3) alkali salts of derivatives at thiol groups of decomposition products obtained by reduction of keratin material: 0.05-10.0 wt.%.

#### **DE-C-29 40 220 (D5)**

The equivalent to DE-C-29 40 220 is US 4,279,996, copy of which is enclosed. Both documents are almost identical, except the claims and an additional prior art section in DE-C-29 40 220 on page 2, lines 23 to 42 citing the prior art mentioned on the cover page of DE-C-29 40 220 which came up during examination of DE-C-9 40 220.

The claims of DE-C-229 40 220 read as follows:

1. The use of a water-soluble keratin hydrolysate for application to the hair as an could waving lotion having at least two mercapto groups in one molecule and having an average molecular weight of 2,000 to 20,000 prepared by reducing keratin in an aqueous solution of a reducing agent selected from the group consisting of mercaptan and sulfides under alkaline conditions, removing the reducing agent from the resulting reduction product and then subjecting the reduction product to enzymatic hydrolysis in an aqueous medium in the presence of an enzyme selected from the group consisting of pepsin, bromelin, thermolysin, trypsin and chymotrypsin, wherein the hair is waved not having an influence on the disulfide bridge bounds of the hair and the waving lotion is an 0.5 to 6.0 wt.% water solution of the keratin hydrolysate in which a water soluble metal compound as a catalyst, a surface active agent or a volatile alkaline substance can be incorporated, and the waving of the hair is carried out by applying the

manufactured lotion on the hair, coiling the hair on sticks and drying using a dryer or applying an neutralization solution comprising an oxidation agent to the hair after the hair drying if necessary, to speed up the oxidation of the keratin hydrolysate.

2. The use of claim 1, wherein the waving lotion is a 0.5 to 4 wt...% keratin hydrolysate solution in a solvent composition of water and 5 to 10 wt...% alcohol.

## **DE-A1-40 09 617 (D6)**

The abstract and the claims of DE-A1-40 09 617 read as follows:

### Abstract:

Hair-treatment agents in the form of preparations in aqueous, aqueous-alcoholic or emulsion form, with a content of cationic surface-active compounds, contain a combination of polyvinyl pyrrolidone and a water-soluble oligo- or polypeptide as the active substance which increase the elasticity and strength of the hair and reduce damage due to splitting of hair. Preferably, the hair-treatment agents are in the form of an aqueous dispersion containing 1-5 wt.% of a fat, 0.1-5 wt.% of a surface-active quaternary ammonium, pyridine or imidazole compound, 0.1-4 wt.% of polyvinyl pyrrolidone and 3-5 wt.% of a protein hydrolysate.

### Claims:

1. Hair-treatment agents for the treatment of strained hair in the form of preparations in aqueous, aqueous-alcoholic or emulsion form, with a content of cationic surface-active compounds, wherein said agents are a combination of 0.1-4.0 wt.% of polyvinyl pyrrolidone and 0.1-5.0 wt.% of a water-soluble oligo- or polypeptide.
2. Hair-treatment agents of claim 1, wherein the cationic surface-active compounds are quaternary ammonium, pyridine or imidazole compound with a content of 0.1-5 wt.%.
3. Hair-treatment agents of claim 1 or 2, wherein the agent is a aqueous dispersion with a content of 1-20 wt.% fatty compound selected from the group consisting of paraffin, C<sub>14</sub>-C<sub>22</sub> fatty alcohols, C<sub>14</sub>-C<sub>22</sub> fatty acids, fatty acid-fatty alcohol esters from C<sub>12</sub>-C<sub>22</sub> fatty alcohols and fatty acids, C<sub>16</sub>-C<sub>44</sub> dialcylesters, fatty acid esters of ethylene glycol, propylene glycol, or glycerine of C<sub>12</sub>-C<sub>22</sub> fatty acids, 0.1-5 wt.% cationic surface-active quaternary ammonium, pyridine or imidazole compound, 0.1-4.0 wt.% of polyvinyl pyrrolidone and 0.1-5.0 wt.% of a water-soluble oligo- or polypeptide of a protein hydrolysate.
4. Hair-treatment agents of claims 1 to 3, wherein the water-soluble oligo- or poly-peptide is an elastin hydrolysate.

The description of DE-A1-40 09 617 provides some additional information as follows:

Water-soluble oligo- or polypeptides are defined in the description (page 2, lines 33, 34) as all proteins and their decomposition products soluble in water up to at least 0.5 wt.%. Decomposition products include for example hydrolysates not completely decomposed to amino acids (page 2, lines 34, 35). DE-A1-40 09 617 points to prior art hydrolysates having an average molecular weight of 400 to 20,000 Dalton, preferably 800 to 6,000 Dalton (page 2, lines 44 to 46). The hydrolysates are obtained from different protein sources, e.g. from elastin, casein, albumin, sericin, collagen or keratine (page 2, lines 40-42).

### **DE-A1-197 52 837 (D8)**

The abstract and the claims of DE-A1-197 52 837 read as follows: Abstract:

The invention relates to the use of polyethylene imines for reinforcing the setting properties of hair treatment agents and for improving the mechanical properties of keratinous fibres. The invention also relates to agents which improve the condition of and strengthen hair or which set hair using a combination of PEI and cationic or non-ionic polymers.

#### Claims:

1. The use of polyethylene imines for reinforcing the setting properties of hair treatment agents and for improving the mechanical properties of keratinous fibers.
2. Aqueous agent comprising usual cosmetic compounds, wherein said agent further comprises a) 0.05 to 5 wt.% polyethylene imines b) 0.01 to 5 wt.% cationic polymers for the treatment of keratinous fibers.
3. Hair treatment agent of claim 2, wherein the polyethylene imines has a molecular weight of 500 to 20000  $\text{gmol}^{-1}$ , preferably 1000 to 10000  $\text{gmol}^{-1}$  in particular preferably 1000 to 5000  $\text{gmol}^{-1}$  with a content of 0.05 to 4 wt.%, preferably 0.1 to 2 wt.% and in particular preferably 0.1 to 1 wt.%.
4. Hair treatment agent of claim 2 or 3 with a content of 0.02 to 4 wt.%, preferably 0.05 to 2 wt.%, in particular preferably 0.1 to 1.5 wt.% cationic polymers.
5. Hair treatment agent of one of claims 2 to 4, wherein said agent further comprises at least one compound of the panthenol group and its derivatives with a content of 0.05 to 5 wt.%, preferably 0.1 to 2 wt.% and in particular preferably 0.1 to 1 wt.%.
6. Aqueous agent comprising usual cosmetic compounds, wherein said agent further comprises as hair consolidating agents a) 0.05 to 5 wt.% polyethylene imines b) 0.05 to 5 wt.% non-ionic polymers for the treatment of keratinous fibers.
7. Hair treatment agent of claim 6, wherein the polyethylene imines has a molecular weight of 500 to 20000  $\text{gmol}^{-1}$ , preferably 1000 to 10000  $\text{gmol}^{-1}$  in particular preferably 1000 to 5000  $\text{gmol}^{-1}$  with a content of 0.05 to 4 wt.%, preferably 0.1 to 2 wt.% and in particular preferably 0.1 to 1 wt.%.

8. Hair treatment agent of claim 6 or 7 with a content of 0.02 to 4 wt.%, preferably 0.075 to 2 wt.%, in particular preferably 0.1 to 1.5 wt.% non-ionic polymers.

Hair treatment agent of one of claims 6 to 8, wherein the non-ionic polymer is polyvinylpyrrolidone or a vinylpyrrolidone/vinylacetate-copolymer.

9. Hair treatment agent of one of claims 6 to 8, wherein the non-ionic polymer is a homopolymer or a vinylcaprolactam.
10. Hair treatment agent of one of claims 6 to 8, wherein the non-ionic polymer is a poly(N-vinylamide).
11. A method for the treatment of human or animal hairs, wherein an agent of one of claims 2 to 11 is applied to the hairs and remains thereon until the next hair washing.

The description of DE-A1-197 52 837 provides some additional information:

Protein hydrolysates of animal origin, such as keratin hydrolysates, are mentioned on page 4, line 52 among the long list of optional additional additives (page 4, line 32 to page 5, line 12).

The hair-repair-liquids E2 and V3 in table 4 comprise "Promois WK" (line 6), which is a keratin hydrolysate having a molar mass of  $400 \text{ g mol}^{-1}$  (page 7, line 40).

#### **German encyclopedia "Rompps Chemie Lexikon", (D9)**

D9 is an online-excerpt from the German encyclopedia "Rompps Chemie Lexikon", wherein the term "precipitation" is defined as a method, wherein a dissolved substance is caused to be separated in form of an insoluble precipitate upon adding an precipitant. As an example the reaction  $\text{AgNO}_3 + \text{NaCl} \rightarrow \text{AgCl} + \text{NaNO}_3$  is provided.

#### **Elod E. et al., Struktur und Reaktionsfahigkeit der Wollfaser, Meiland Tex-tilberichte 1942, pages 313-316 (DII)**

This is a scientific article about the oxidizing effect of hydrogen peroxide on wool. In particular, it is shown, that wool fibers treated with hydrogen peroxide for 8 or 24 hours at  $80^\circ\text{C}$  (table 2) fractionalize as shown in Fig. 4.

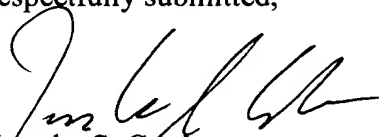
The summary ("Zusammenfassung") on page 316 reads as follows:

1. It has been analyzed the action of aqueous, diluted  $\text{H}_2\text{O}_2$  solutions on wool yarn. All cystine has been converted by the treatment with a  $\text{H}_2\text{O}_2$  solution having a concentration of 2.42 wt.% for 8 hours at  $80^\circ\text{C}$ .
2. During the oxidation increasing amounts of nitrogenous compounds not having high molecular character are going into solution. From this follows that also peptide bounds are cleaved.



3. The number of free amino groups of the yarns treated with hydrogen peroxide decreases substantially and shows thereby a substantial decrease of the number of salt bonds.
4. Oxidized wool reacts acidic in increasingly measures. This can be concluded from the shift of the isoelectric point, increased NaOH absorption and increasing alkali solubility.
5. A comparison of the mechanical stability and the measured values for the chemical changes teaches that the cystine analyses as well as the titration of the free amino groups are suitable for the identification of the degradation damages. In case of gentle exposure the determination of the alkali solubility is preferred.
6. Structural analyses at heavily oxidized preparations show the presence of d-keratin.

Respectfully submitted,



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Mark E. Van Dyke et al.

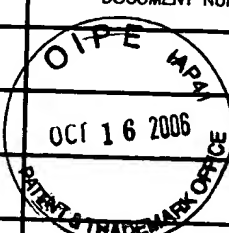
FILING DATE

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GROUP ART UNIT

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE



**U.S. PATENT APPLICATION PUBLICATIONS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
B39	DE 2940220 C2		Germany				✓
B40	DE 3233665 A1		Germany				✓
B41	DE 4009617 A1		Germany				✓
B42	DE 19752837 A1		Germany				✓
B43	GB 2121281 A		United Kingdom				

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

	C126	Zitat aus Rompps Chemie Lexikon "Ausfallung"
	C127	CTFA International Cosmetic Ingredient Dictionary, Fourth Edition, page 248, 1991

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**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
B44	GB 692,478	06/10/53	United Kingdom				
B45	RU 2007181 C1	1991	Russian Federation				✓

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

	C128	"Struktur und Reaktionsfahigkeit der Wollfaser," Meiland Textiberichte, 1942, 7, 313-16
	C129	Blackburn et al., "The action of organic acids on some fibrous proteins: the oxidation of wool keratin," Biochemical Journal, Vol. 49, 554-57, 1951

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						YES	NO

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

		C130	Response to Opposition filed March 23, 2006 in European Patent 1 265 570

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